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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITCHELL, GREGORY W	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,134	BURNETT ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/01/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed August 01, 2005. Claim 1 has been cancelled. Claims 39-83 have been added, are pending and are examined herein. Applicant's amendments have necessitated the withdrawal of the rejections set forth in the Office Action dated June 15, 2005. The following rejections now apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-62, 64, 66-71, 74-75, 77-80 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (USPN 5993787).

Sun et al. teach anhydrous topical preparations with good physical stability and excellent cosmetic attributes comprising propylene carbonate; one or more short chain alcohols and/or glycols, such as ethanol, isopropanol, propylene glycol, polyethylene glycol, etc.; glycerol (glycerin); and an active ingredient (Abstract). The topical preparations are formulated as, e.g., gels (col. 3, lines 14-19). Active ingredients are selected from antifungal agents, such as miconazole nitrate, ketoconazole, etc. (col. 6, lines 1-12). Additional components, such as pigments, ascorbic acid, BHT, chelating agents, hydroxypropyl cellulose, etc. are taught to be useful therein (col. 4, lines 9-13;

col. 8, lines 20-65; col. 9, lines 17-28). Emollients such as Arlamol E® (PPG-15 Stearyl Ether) are also taught to be useful therein (col. 10, lines 61-67; col. 16, lines 19-37). Antifugal agents (miconazole nitrate) are exemplified in concentrations of 2%; propylene glycol is exemplified at 20%; BHT is exemplified at 0.05%; glycerol is exemplified at 20%; chelating agents are taught at 0.1-10%; PPG-15 stearyl ether is exemplified at 2% (col. 8, lines 42-49; col. 10 line 32-col. 11, line 3). The treatment of athlete's foot (tinea pedis), ring worm (tinea corporis), jock itch (tinea cruria) and the administration to human skin is taught (col. 2, lines 38-58; col. 9, line 60-col. 10, line 5). Use of the compositions against *T. rubrum*, specifically, is also taught (col. 12, line 46-col. 14, line 5). Sun et al. does not specifically exemplify the combinations as herein envisioned.

It would have been obvious to one of ordinary skill in the art at the time of the invention comprising the glycols and alcohols as herein envisioned because Sun et al. teaches that one or more of such glycols and/or alcohols may be used in the anhydrous preparations described therein. Furthermore, Sun et al. specifically exemplifies combinations of alcohols and/or glycols in the anhydrous preparations. It would have been obvious to one of ordinary skill in the art to utilize ketoconazole as the antifungal agent in the compositions exemplified in Sun et al. because Sun et al. envisioned miconazole nitrate and ketoconazole to be interchangeable agents thereas. Accordingly, one of skill in the art would have been motivated to formulate the composition as claimed in order to prepare a topical antifungal composition with good physical stability and excellent cosmetic attributes suitable for the treatment of athlete's foot, ring worm and jock itch, as taught by Sun et al.

It is noted that the solubilization of the ketoconazole is a function of the amounts of components in the system. Accordingly, since the concentrations of components as claimed is the same as taught by the prior art, the degree of solubilization of ketoconazole would be same in the prior art composition as the composition claimed.

It is noted that the components useful herein are disclosed, generally, as being useful in the invention of Sun et al. Accordingly, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of said components to arrive at the concentrations as herein envisioned. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 63, 65 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. as applied to claims 39-62, 64, 66-71, 74-75, 77-80 and 83 above, and further in view of Kabara (USPN 5208257).

Sun et al. apply as disclosed above. Sun et al. teach that the use of a chelating agent increasing the wrinkle regulating benefits of the compositions disclosed therein (col. 8, lines 33-41). The reference fails to teach the use of citric acid.

Kabara teaches a topical antimicrobial composition (Abstract). Chelating agents, such as citric acid are taught to be useful therein (col. 7, line 64-col. 8, line 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize citric acid in a composition of Sun et al. because (1) both Sun et al.

and Kabara are directed to antimicrobial topical compositions; (2) Sun et al. teach the addition of a chelating agent increases the wrinkle regulating benefits of the compositions disclosed therein; and (3) Kabara teaches citric acid as a chelating agent. One would have been motivated to add citric acid to the composition of Sun et al. in order to increase the wrinkle regulating benefits of the composition, as taught by Sun et al.

It is pointed out that for purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation "consisting essentially of", Applicant as the burden of showing that the introduction of additional steps or components would materially change the characteristics of Applicant's invention. See MPEP 2111.03.

Claims 76 and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. as applied to claims 39-62, 64, 66-71, 74-75, 77-80 and 83 above, and further in view of Thornfeldt (USPN 5231087).

Sun et al. apply as disclosed above. The references does not specifically teach a method of treating seborrheic dermatitis.

Thornfeldt teaches that *P. ovale* has been shown to play a significant role in seborrheic dermatitis. It is also taught that ketoconazole is known for the treatment of seborrheic dermatitis (col. 2, lines 44-60).

It would have been obvious to one of ordinary skill in the art to utilize the composition rendered obvious by Sun et al. in a treatment of the *P. ovale* related skin disorder seborrheic dermatitis in humans because (1) the compositions of Sun et al. are disclosed to comprise antifungal agents such as ketoconazole, and (2) Thornfeldt teaches that ketoconazole is capable of treating seborrheic dermatitis. One would have been motivated to treat seborrheic dermatitis with such a compositions because, as taught by Thornfeldt, ketoconazole has been reported to improve or clear seborrheic dermatitis lesions in about 75% of patients (col. 2, lines 44-60).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22 and 25-26 of U.S. Patent No. 6,238,683 ('683). Although the conflicting claims are not identical, they are not patentably distinct from each other because '683 claims an anhydrous

composition comprising 1-50% propylene glycol, 10-80% PEG and glycerin, an aqueous vehicle and ketoconazole. See claim 1. The medicaments are solubilized. See claim 2. The vehicle is selected from an alcohol. See claim 3. Emollients, chelating agents, pH adjusters (e.g. citric acid, ascorbic acid, etc.), antioxidants (e.g. BHT), gelling agents, viscosifiers (e.g. hydroxypropyl cellulose), colorants, etc. are also claimed. See claims 8-11. For the claimed concentrations, see claims 12-16, 22 and 25-26.

Claims 74-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22 and 24-26 of U.S. Patent No. 6,238,683 ('683) in view of Thornfeldt (USPN 5231087). For discussion on the claimed compositions, see the rejection above. Claim 24 of '683 claims a method of administration of the composition disclosed in '683. Thornfeldt teaches that *P. ovale* has been shown to play a significant role in seborrheic dermatitis. It is also taught that ketoconazole is known for the treatment of seborrheic dermatitis (col. 2, lines 44-60). Accordingly, it would have been obvious to one of ordinary skill in the art to treat seborrheic dermatitis with a composition comprising an agent known in the art to be useful in the treatment thereof.

Double Patenting

Claims 39-83 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-53, 56-62 and 86-118 of copending Application No. 09/562,376 ('376). Although the conflicting claims

are not identical, they are not patentably distinct from each other because the claims of '376 are substantially similar to those of the instant invention. The only difference between '376 and the instant invention is that '376 lacks a limitation that a retinoid is not present. Furthermore, is no indication in '376 that a retinoid need be added. Accordingly, it would have been obvious to one of ordinary skill in the art to prepare the claimed composition and to utilize it in the same manner as claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments insofar as they address the fact that the rejections set forth in the Office Action dated June 15, 2005 are directed to a cancelled claim are persuasive. As a result of the cancellation of claim 1, the rejections set forth in the previous Office Action have been withdrawn. Accordingly, the new rejections, set forth above, were necessitated by Applicant's amendments.

Applicant's arguments that Sun et al. does not apply because "Sun clearly states that propylene carbonate is an essential component in the described compositions." This argument is not persuasive insofar as it is directed to claims 39-72 and 74-83 because said claims have the open claim language of "comprising". Accordingly, a composition comprising the same components as well as another component are within the scope of the claims. As far as the argument is directed to claim 73, it is not persuasive because Applicant has not shown that the addition of propylene carbonate

to the claimed invention would "materially change the characteristics of Applicant's invention." Indeed, Applicant claims a composition wherein the ketoconazole is "solubilized" (claim 40) and Sun et al. indicates that the purpose of using propylene carbonate is for its "considerable solubilization properties." Accordingly, Applicant has not provided sufficient evidence to differentiate the claimed composition from that of the prior art.

Applicant argues, "After reading Sun, a person of ordinary skill in the art would clearly have no reasonable expectation of success in preparing a composition that did not include propylene carbonate as a component." As stated above, there is no limitation in the pending claims that propylene carbonate be excluded.

Applicant's suggested Terminal Disclaimer over '683 would be sufficient to overcome the obviousness type double patenting rejection made therewith. The rejection will be maintained, however, until such a time as the Terminal Disclaimer is filed.

Applicant's cancellation of the pending claims I '376 would be sufficient to overcome the provisional obviousness type double patenting rejection made therewith. The rejection will be maintained, however, until such a time as the such claims are cancelled.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER